Date: July2000 (Rev)
Revised Date(s): July, 9, 2008
June 15, 2011

CRITERIA FOR PRIOR AUTHORIZATION

Becaplermin 0.01% gel (Regranex®)

PROVIDER GROUP: Pharmacy

MANUAL GUIDELINES: The following drug requires prior authorization.
Becaplermin 0.01% gel (Regranex®)

CRITERIA for becaplermin: (must meet all of the following)

- Patient must have lower extremity diabetic neuropathic ulcer(s) that extend into the subcutaneous tissue or beyond (Stage III or IV).
- Patient must be 16 years of age of older.
- Ulcer(s) must have adequate blood supply.
- Ulcer(s) must be treated with good ulcer care practices including:
    - Initial sharp debridement has been done.
    - Off-loading of pressure on the ulcer(s) has been accomplished.
    - Ulcer(s) is not infected or the infection is being managed with an anti-infective therapy.

RENEWAL CRITERIA for becaplermin: (must meet initial prior authorization criteria in addition to the following)

- There must be a measurable improvement in the ulcer(s).
    - There must be a 30% reduction in size of ulcer after 10 weeks of treatment or complete healing after 20 weeks.
    - If multiple ulcers are involved there must be a 30% reduction in size in at least 50% of the ulcers (ex. If there are 3 approvable ulcers, 2 of the 3 ulcers must show a 30% reduction in size for renewal).

Prior authorization may be approved for ***up to a maximum of 3 tubes in a lifetime***.

Warning: An increased rate of mortality secondary to malignancy was observed in patients treated with 3 or more tubes of Regranex gel in a post marketing retrospective cohort study. Regranex gel should only be used when the benefits can be expected to outweigh the risks. Regranex gel should be used with caution in patients with known malignancy.